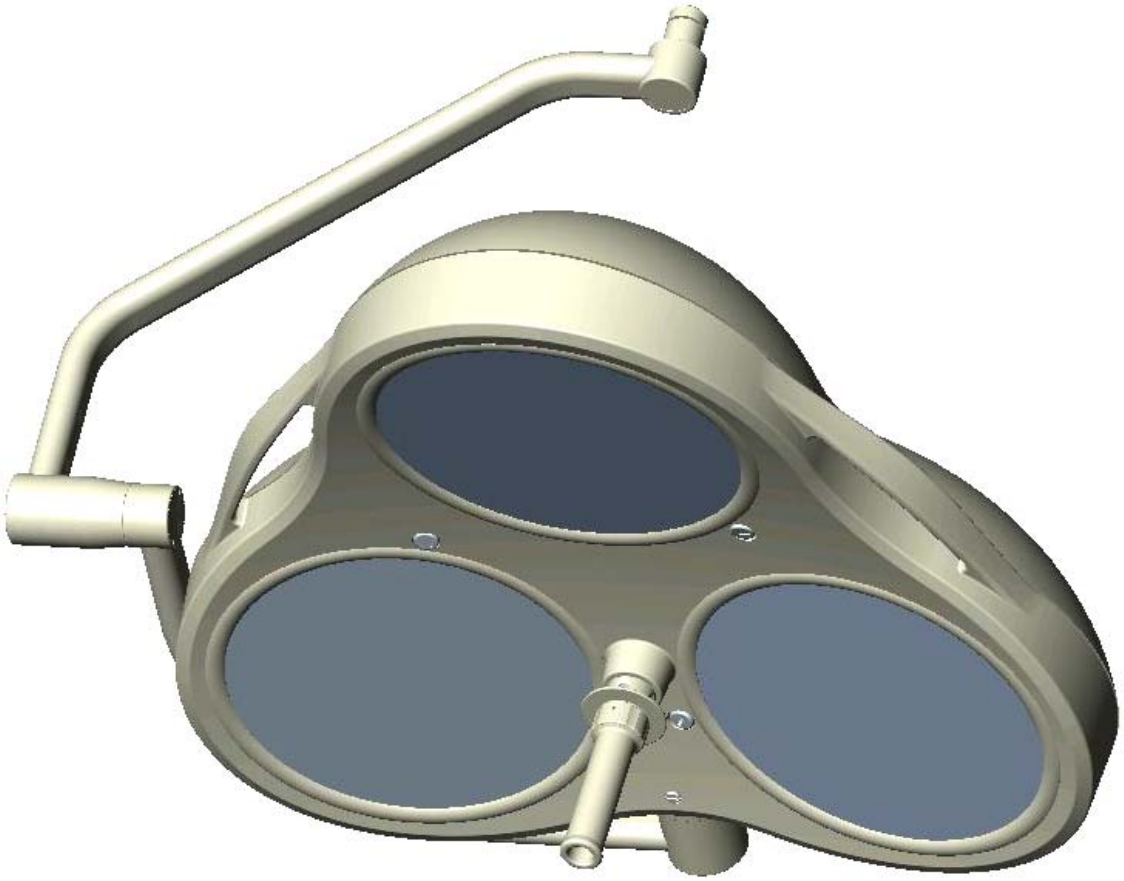
Instructions for use

MACH M5



Mach M5 ceiling lamp for room heights up to 2,8m, F- / F/H / DF- / DF/H-model
Mach M5 ceiling lamp for room heights between 2,8m – 3m, F- / F/H / DF- / DF/H-model

Dr. Mach **GmbH u. Co., Floßmannstrasse 28, D-85560 Ebersberg**
Tel.: +49 (0)8092 2093 0, Fax +49 (0)8092 2093 50
Internet: www.dr-mach.com, E-Mail: info@dr-mach.de

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Dear customer!

Congratulations for acquiring our new OT-lamp **MACH M5**.

The **MachVISION** optical system provides an illuminated field with improved contrast and excellent homogenity. Combined with the **Duo-Focus** feature this offers a unique possibility for adaptation to the wound area.

With this lighting system you profit from a whole range of new developments, based on 50 years of experience in the production of operating and doctor's lights.

The lighting system is characterised by a previously unreceivable general colour rendition value of Ra = 96. In other words, the colours are **reproduced naturally** and in **high contrast**. The wound area is shown in a **comfortable** light.

The different reds of a wound area can now be recognised very precisely. For the doctor or surgeon this means a considerable improvement in the recognition of **details** in the **wound area**.

The R96 lighting system uses computer-optimised cold-light filters that reduce both the **unwanted build-up of heat in the head area and the heat radiated on the illuminated wound area to a minimum**.

Pay attention to the special mounting instructions for ceiling lamps.

All information quoted here relates only to the illuminants. Details of ceiling or wall installation can be found in the mounting instructions.

1. Safety instructions

Pay attention to the instructions for use when handling the lamp.

WARNING:

This device has not been designed for use in potentially explosive areas.
According to the Medical Device Regulation the lamp is classified under class I.

Store the OT-lamp in its package for at least 24 hours in the respective room before mounting, in order to equal temperature differences.

Please read the instructions for use carefully to make the most of your lighting system and to avoid any damages to the device.

The lamps may only be repaired and special assembly work may only be carried out on the reflector or sockets by ourselves or a company that has been expressly authorised by us.

The manufacturer can only be made responsible for the safety of the lamp if repairs and alterations are carried out by the manufacturer himself or a company that guarantees to observe the safety regulations.

The manufacturer cannot be made liable for personal or material damages if the lamp is operated inexpediently or incorrectly or used for purposes other than those for which it is intended.

The lamp is to be dismantled from the spring arm in reverse order to its assembly. This may only be carried out after the spring arm has been adjusted in height at horizontal position since the arm is under spring tension and can bounce up.

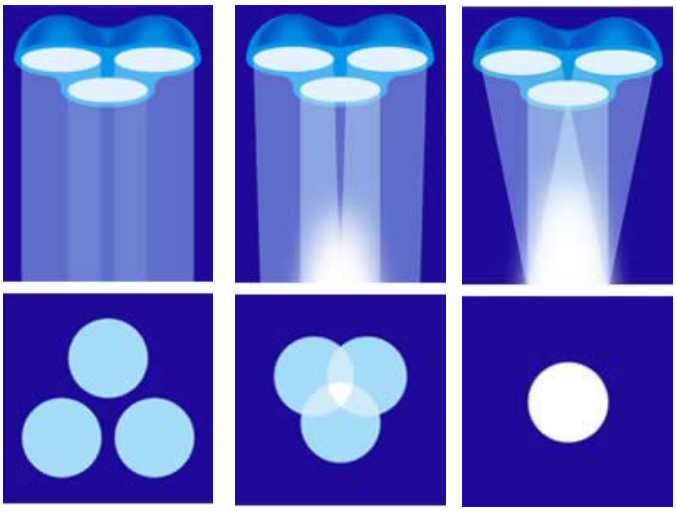
Make sure that the lamp is in perfect working order before every use.

Attention, external transformer!
The lamp works only with an external transformer 300VA.
The external transformer (Order No. 6701 0208) must be tested and validated according to IEC 60601-1.
If the external transformer is not tested and validated according to IEC 60601-1, it is not allowed to use it with Dr. Mach OT-lamps.

2. Operating the lamp MACH M5

2.1 Brief description of the lamp

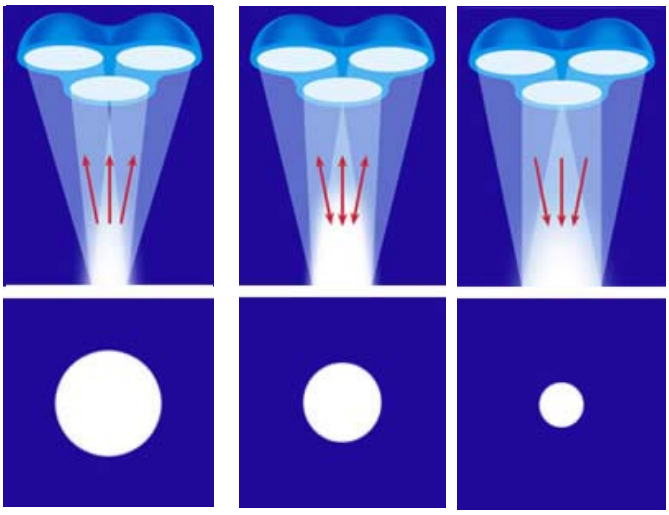
The OT-lamp MACH M5 is available in following versions:
- Standard OT-lamp (F) with merging of light fields
- Duo-Focus OT-lamp (DF) with merging of light fields and focusing
- F- or DF- lamps with light intensity control (/H)



2.1.1 Merging of light fields (F- model)

The **F-model** offers light field adjustment by **merging the individual light fields** of each reflector by swiveling them.

NOTE: This feature is activated by turning the sterilisable handle.



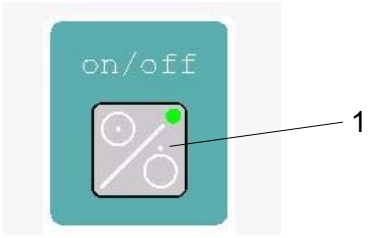
2.1.2 Focusing (DF- model)

The **DF-model** offers a second **additional** facility to further adjust the illuminated field to an extra small or extra large size, depending on the specific requirements, by **focusing through moving the bulbs up or down**.

NOTE: This feature is activated by turning the ring at the top of the sterilisable handle.

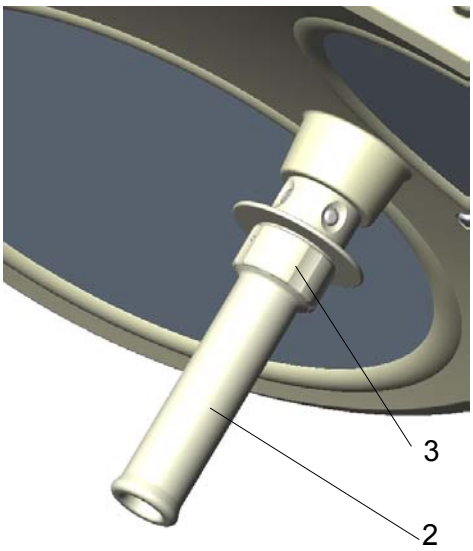
2.1.3 Light intensity control (/H- model)

The OT-lamp models offer an optional feature, the light intensity control.
You can adjust the light intensity between 50% and 100%; according to your requirements.



2.2 Turning the lamp ON/OFF

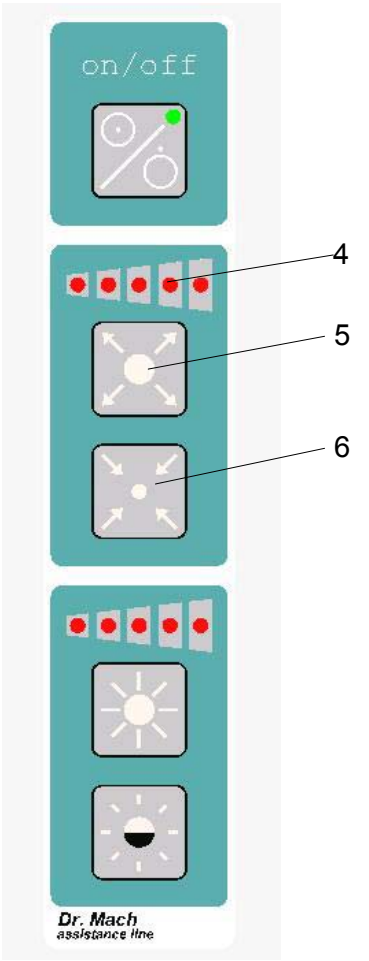
The **F- and DF-models** are switched ON/OFF at the main switch of the OT or at the ON/OFF switch at the cardan bow (if ordered).
The **F/H and DF/H models** are switched ON/OFF with the **touch-button 1** at the key-pad of the lamp.



2.3 Adjusting the illuminated area by merging the light fields (for F- and F/H-models)

All F and F/H lamp models offer the feature of "merging the light fields". This feature is activated by turning the **sterilisable handle 2**.

Remark:
The ring 3 has no function here.



2.4 Adjusting the illuminated area by merging the light fields and focusing – Duo-Focus system (for DF- and DF/H-models)

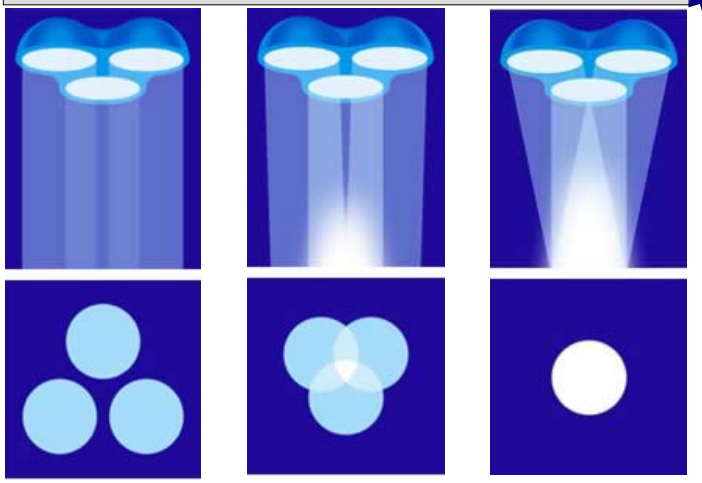
DF- and DF/H-models also have a "**focusing**" function (Duo-Focus).
The combination of merging the light fields and focusing (**Duo-Focus system**) enables the ideal adjustment of the light field to the wound area in a range from 8cm to 35cm diameter. Such a large range of adjustment is not possible with conventional technique.

To activate the focusing function turn the **adjusting ring 3** on the handle, or – if the lamp is equipped with a keypad at the cardan bow (for DF/H-models) – press **touch buttons 5 and 6**.

Press **touch button 5** to expand the focus and **touch button 6** to bundle the light to a minimum area. The current focused diameter is shown in the **LED-display 4**.

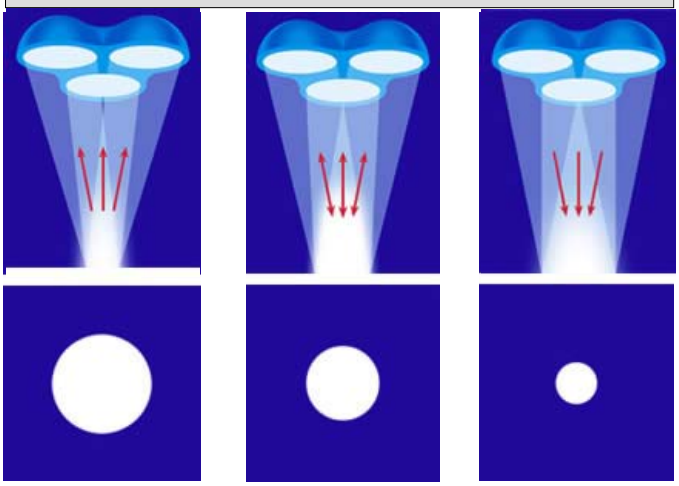
2.5 Overview of the lamp functions
Merging of light fields and focusing

MERGING OF LIGHT FIELDS

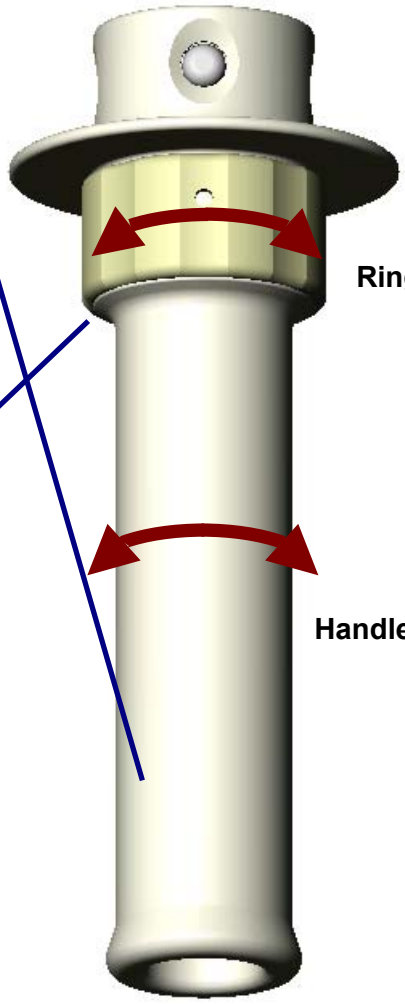


Merging the individual light fields of each reflector is done by swivelling the reflectors. The light fields overlap.
This feature is activated by **turning the sterilizable handle (1)**.

FOCUSING

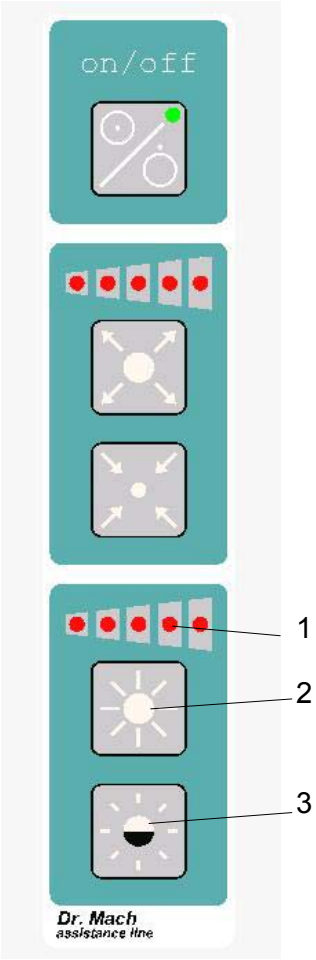


Focusing is done by moving the bulbs inside the reflectors up or down. This way you can further adjust the illuminated field to an extra small or extra large size, depending on the specific requirements.
This feature is activated by **turning the ring (2) at the top of the sterilisable handle**.



*Always activate **merging of light fields** first by turning the handle (1), then activate **focusing** when necessary by turning the ring (2).*

Key pad



2.6 Adjusting the light intensity (for F/H- and DF/H-models only)

Select the desired light intensity before the operation.

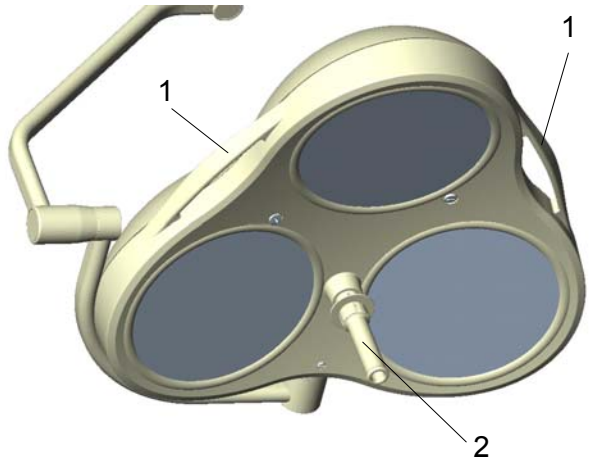
At these models the adjustment is done by the keypad at the cardanic bow. The intensity can be adjusted continuosly between 50% and 100%.

Press **push button 2** to **increase** the light intensity and press **push button 3** to **reduce** the light intensity.

The set light intensity is shown by **LED-display 1**.

For other light models we recommend a dimmer in the supply line.

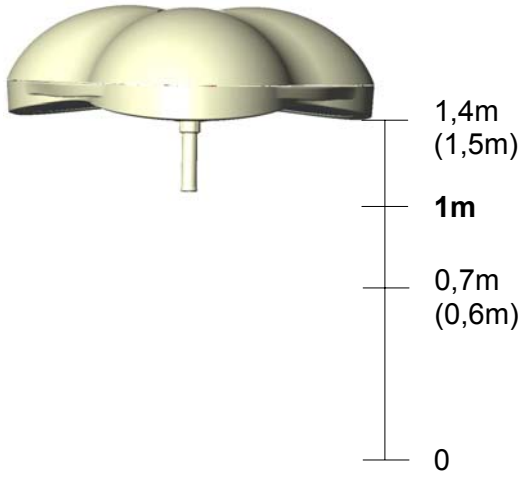
2.7 Positioning



Use the **sterile handle 2** or the **handle rails 1** to position the lamp.

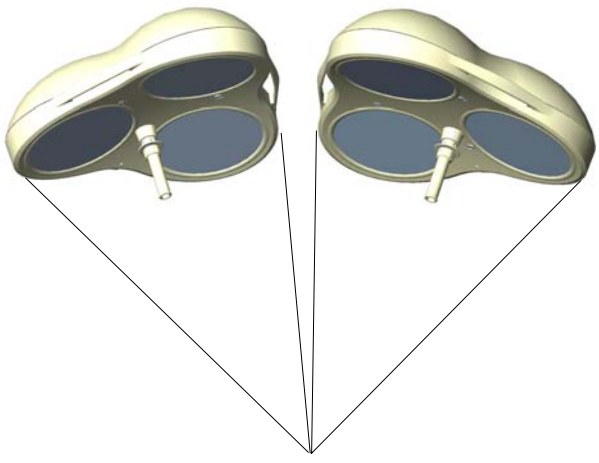
Use the **handle rail** to position the lights before the operation.

Use the **sterile handle** for positioning during the operation. This handle can be removed for sterilisation.



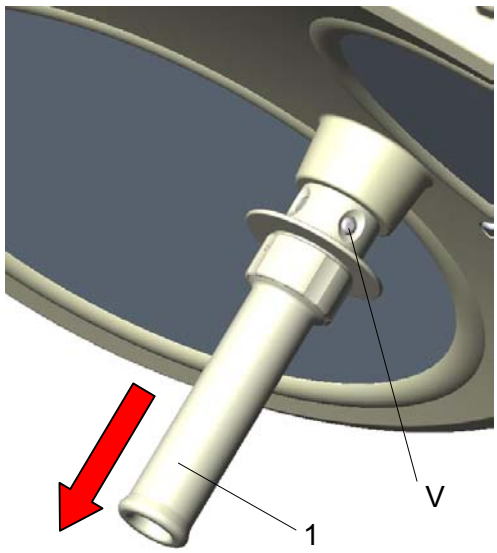
The working distance for the F-lamps is 0,7m to 1,4m.
The working distance for the DF-lamps is 0,6m to 1,5m.

The handle is supplied with a detectable mechanical catching. When the handle catches in this position, the lamp is optimally set for a working distance of 1 meter.



Two or more lamps can be used for an intensive illumination of large operation fields.
It is also possible to illuminate two operation fields simultaneously.

3. Cleaning



3.1 Sterilisable handle

At delivery the lamp is equipped with the handle sleeve 1. The handle sleeve is removable and sterilisable. Before using the first time and before every use the handle sleeve must be cleaned, disinfected and sterilised.

The handle sleeve must be removed for sterilisation:

- To remove press the lock V and pull off the sterilisable handle sleeve 1 while keeping the lock pressed.
- To attach, push on and slightly twist the handle until the lock V engages securely.

Handles often become unsterile during an operation. Therefore always keep additional handles available for exchange.

Cleaning / disinfection and sterilisation

Basics
Efficient cleaning / disinfection is an essential requirement for effective sterilisation of the handle.
Within the scope of responsibility for the sterility of the products it should be noted that only sufficiently validated equipment and product specific processes are used for cleaning / disinfection and that the validated parameters are complied with in every cycle.
In addition, the hospital / clinic hygiene regulations must be observed.

Cleaning / disinfection
Cleaning and disinfection must be carried out immediately after use.
A mechanised process (disinfector) should be used for cleaning / disinfection. The efficiency of the process used must be recognised and validated in principle (e.g. listed under disinfectants and disinfection procedures tested and recognised by Robert-Koch-Institute / DGHM).
When using other procedures (e.g. a manual procedure), proof and process efficiency in principle must be provided within the scope of validation.
Proof in principle of the suitability of the handles for efficient cleaning / disinfection was provided using a cyclic cleaning system (Netsch-Bellmed T-600-IUDT/AN, programme 2 for small parts; code B).

It is not allowed to use agents / disinfectants, which contain the following substances, as these may cause changes in the material:

- High-concentration organic and inorganic acids
- Chlorinated hydrocarbons
- 2-ethoxyethanol

When cleaning / disinfecting, the following procedures must be followed:

	Process	**Time (sec.)**
Zone 1	Pre-rinse, external, cold, 10 – 15°C Washing, acidic, external 35°C Draining time Re-rinse, external approx. 80°C Draining time Re-rinse, external approx. 80°C Draining time	45 120 10 *10 *15 *15 15
Zone 2	Washing, alkaline, external, 93°C Draining time Re-rinse, external, acidic, 90°C Draining time Re-rinse, external 90°C Draining time	135 10 10 15 15 15
Zone 3	Drying, external 100 – 120°C	200
Zone 4	Drying, external 100 – 120°C	200
	Door open / close & transport (sluice discharge)	60
	Cycle time overall ca.	290 ≈ 5 minutes

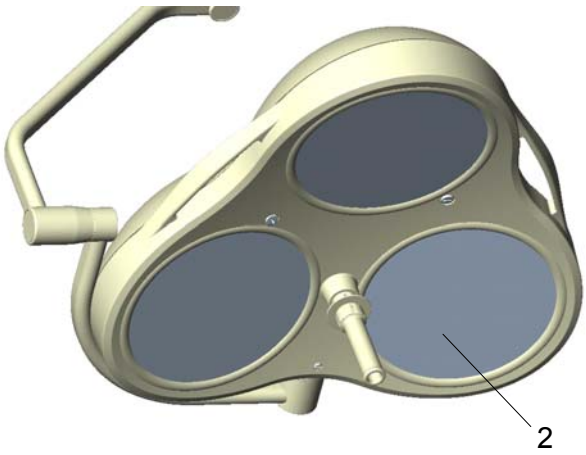
* When occupying the disinfection zone (washing zone 2), the re-rinse and draining times will depend on the respective objects being washed therein!

Sterilisation
Only previously cleaned and disinfected handles may be sterilised.
The handles are placed in a suitable sterilisation pack (one-way sterilisation pack, e.g. foil / paper sterilisation bags, single or double pack) in accordance with DIN EN 868 / ISO 11607 for steam sterilisation and then sterilised.
Use only the sterilisation procedure listed below for sterilisation. Other sterilisation procedures (e.g. ethylene oxide, formaldehyde and low-temperature plasma sterilisation) are not permissible.

Steam sterilisation procedure
Validated in accordance with DIN EN 554/ISO 11134
Maximum sterilisation temperature 134°C

Proof in principle of the handles' suitability for effective sterilisation was provided using a fractional vacuum process (Euroselectomat 666 by MMM Münchner Medizin Mechanik GmbH, sterilising temperature 134°C, holding time 7 min.)

Inspection / durability
The handles should be inspected for damage and changed before re-use, if required.
The handles may be cleaned / disinfected, sterilised and re-used for a maximum of 1000 times. If the handles are re-used more than 1000 times, then this will be the responsibility of the hospital / clinic.



3.2 Lamp housing, dispersing lens and support system

The Dr. Mach OT-lamp system has a high-quality surface, which can be cleaned with conventional cleaning agents.

The **lens system 2** is made of a high-quality plastic. Pay attention to the following during cleaning:

- Never wipe over the **lens system 2** with a dry cloth (always clean with a wet cloth).
- Only use disinfectants with **less than 20% alcohol**.

Alc. ≤ 20 %

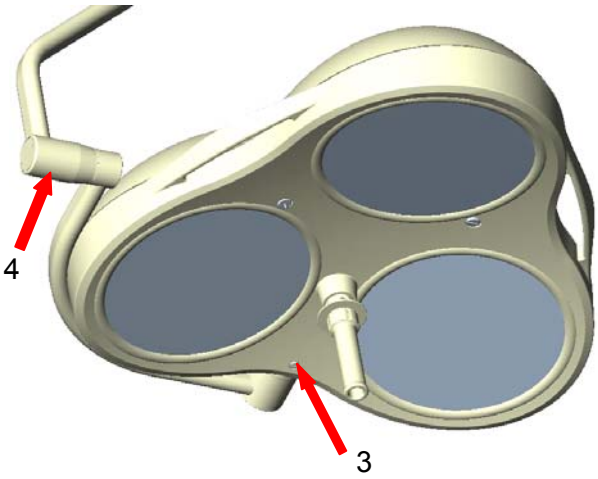
Wipe the **lens system 2** after cleaning with an antistatic, non-fluffy cloth.

4. Maintenance

DR. MACH lamps are supplied with brakes on the suspension fixture and on the lamp housing. Adjust these brakes, if necessary, after installation.
If the lamp is difficult to move or if it does not keep its position, the brake forces should be adjusted.

The lamps and suspension fixtures have been designed and built, so that regular maintenance intervals are not necessary.
In order to keep the system easy-running throughout its life span, we recommend that the hinges should be greased once a year with acid-free grease.
Attention: Before dismounting the lamp, set the height adjustment of the spring arm to horizontal position (see mounting instructions „Ceiling attachment – wall attachment“).

When adjusting the brakes or the hinges at the ceiling attachment, please consult the mounting instructions “**Ceiling attachment with heavy central axis**” or “**Ceiling attachment – wall attachment**”.



4.1 Adjustments at the lamp head

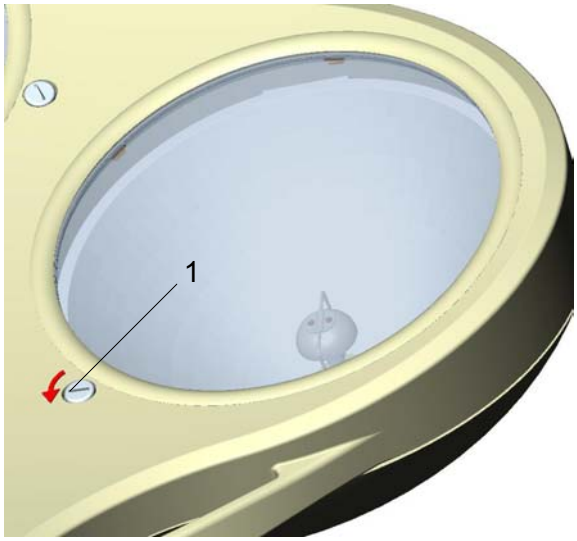
The fine adjustment for handling the lamps can be carried out at **points 3 and 4**.
To adjust the brakes use a screw driver with approriate size.

If you cannot adjust the brakes at **points 3 and 4** as tight as necessary anymore, you will have to replace them.

4.2 Changing of spare parts

4.2.1 Changing the halogen bulbs

Dr. Mach uses special halogen bulbs as illuminants.
Only original Dr. Mach replacement bulbs may be used.
The use of other bulbs can lead to a considerable reduction of the light power and increase in the thermal load.
The halogen bulbs have a service life of approx. 1200 hours. We recommend changing all halogen bulbs in a lamp at the same time to keep maintenance work to a minimum.

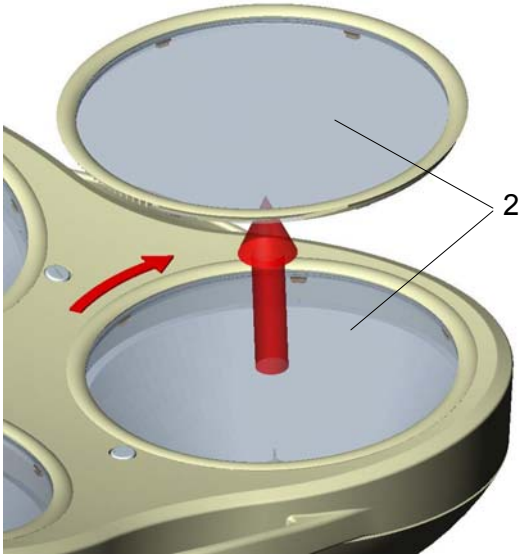


To change the halogen bulbs proceed as follows:

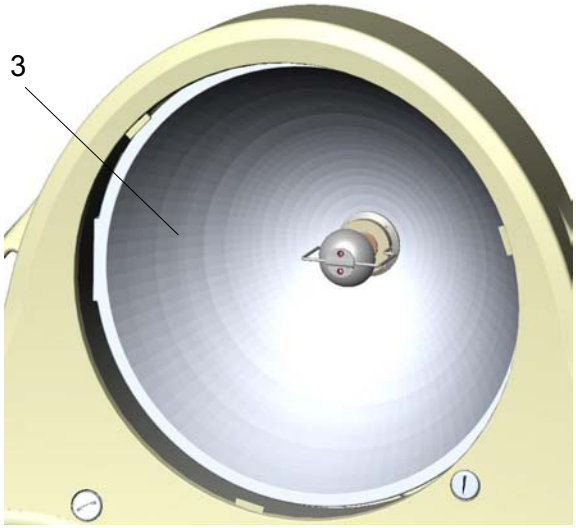
- **Turn off the lamp.**
  ATTENTION: Parts of the housing and the halogen bulb may be very hot immediately after use.

- Turn the lamp, so the light outlets point to the ceiling.
- Turn **screw 1** anticlockwise with an appropriate screw driver.

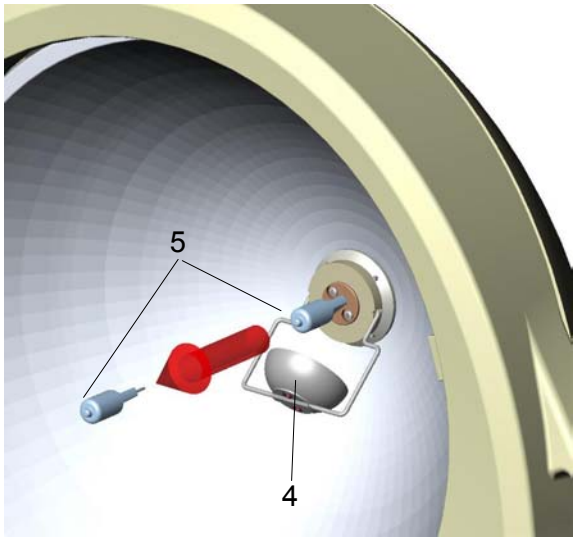
Remark:
In case there is no screw driver available, you can use a coin.



- By turning the **screw 1** anticlockwise, the **optic ring 2** turns clockwise off the lower housing part.
- Remove the **optic ring 2** by pulling it upwards.

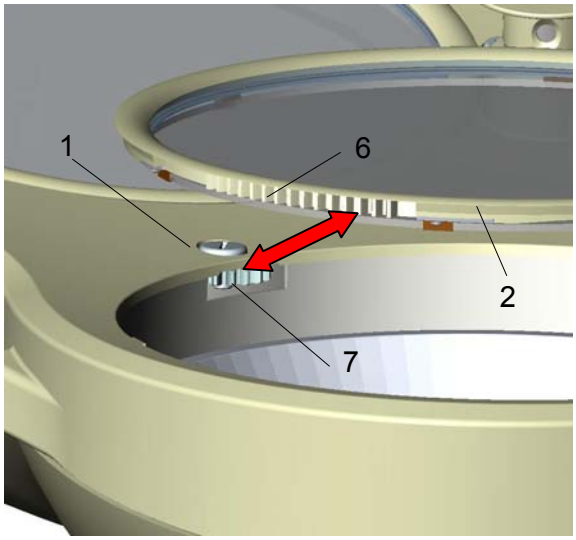


- Now you can see the open **reflector 3** in front of you.
  ATTENTION: Do not touch the inner surface of the reflector, otherwise the surface can be damaged.



- Tilt the **shadower 4** off-center, until it snaps in in the provided groove.
- Pull the **halogen bulb 5** carefully off its socket.

  ATTENTION: Never touch new halogen bulbs with your fingers. Always use the original packaging or a clean cloth.
- Carefully insert the new halogen bulb (22,8V, 77W) in the socket.
- Tilt the **shadower 4** in its original position.



- Mount the **optic ring 2** in reverse order (anti-clockwise rotation).
  For mounting position the **optic ring 2**, so the **toothed wheel segment 6** of the ring and the **toothed wheel 7** in the lower housing part work into each other.
- Fix the optic ring by turning the **screw 1** clock-wise.
- Check the function of the new halogen bulb.

4.2.2 Changing the filter disk

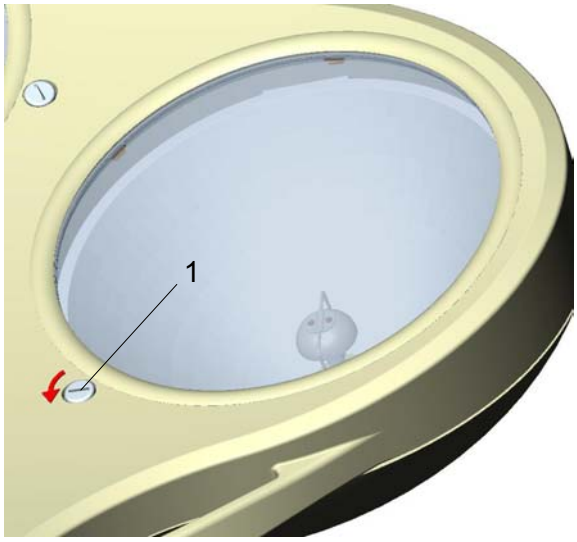
The filter disk between reflector and protective disk prevents a damaging heating of the illuminated area.

ATTENTION!
The lamps must not be used without this filter.

Always place the filter disk on a soft, non-scratching base to preserve its surface.

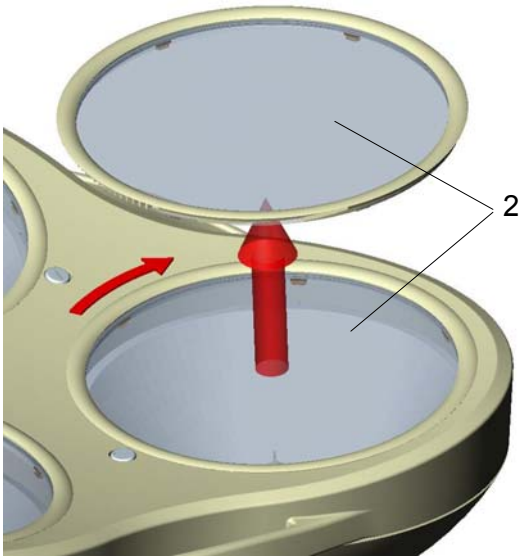
To change the filter disk proceed as follows:

- **Turn off the lamp.**
  ATTENTION: Parts of the housing and the halogen bulb may be very hot immediately after use.

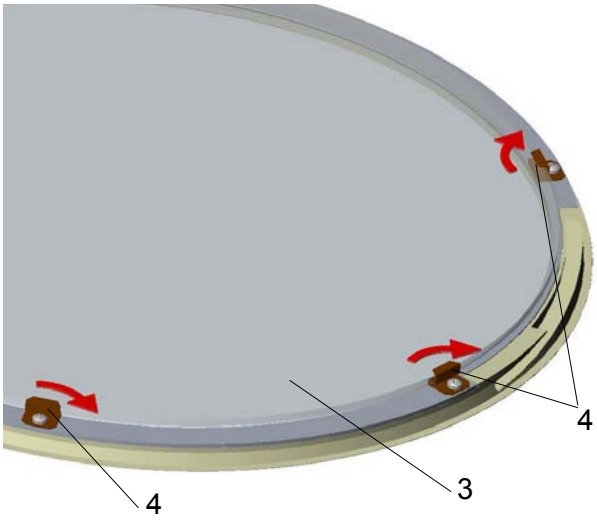


- Turn the lamp, so the light outlets point to the ceiling.
- Turn **screw 1** anticlockwise with an appropriate screw driver.

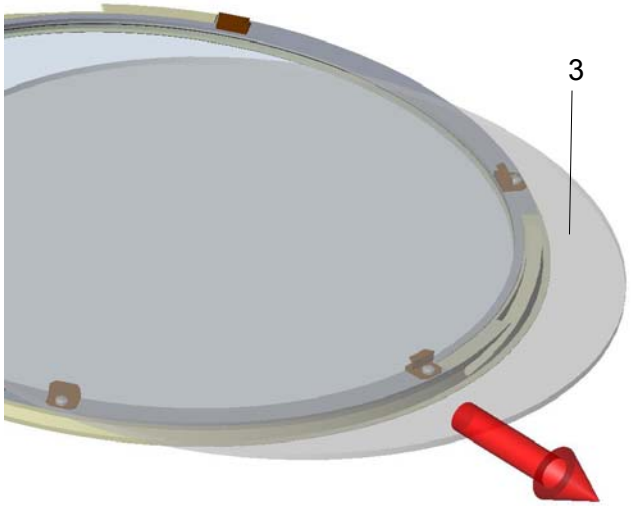
Remark:
In case there is no screw driver available, you can use a coin.



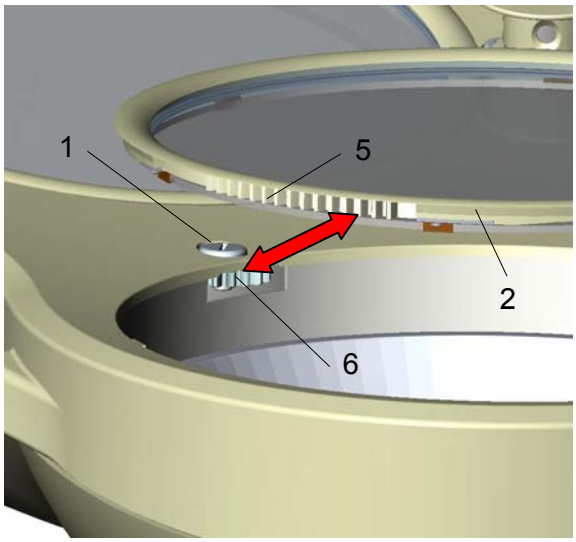
- By turning the **screw 1** anticlockwise, the **optic ring 2** turns clockwise off the lower housing part.
- Remove the **optic ring 2** by pulling it upwards.



- The **filter disk 3** is held by six **retaining angles 4**, the retaining angles are fixed with six recessed head screws.
- Loosen the screws at three adjacent **retaining angles 4** and turn these angles as shown in the left drawing.



- Lift the **filter disk 3** carefully and pull it off the other three retaining angles.
- Mount the new filter disk in reverse order.
  ATTENTION: Only use filter disks that have been cleaned properly (see chapter 3.2).



- Mount the **optic ring 2** in reverse order (anti-clockwise rotation).
  For mounting position the **optic ring 2**, so the **toothed wheel segment 5** of the ring and the **toothed wheel 6** in the lower housing part work into each other.
- Fix the optic ring by turning the **screw 1** clockwise.

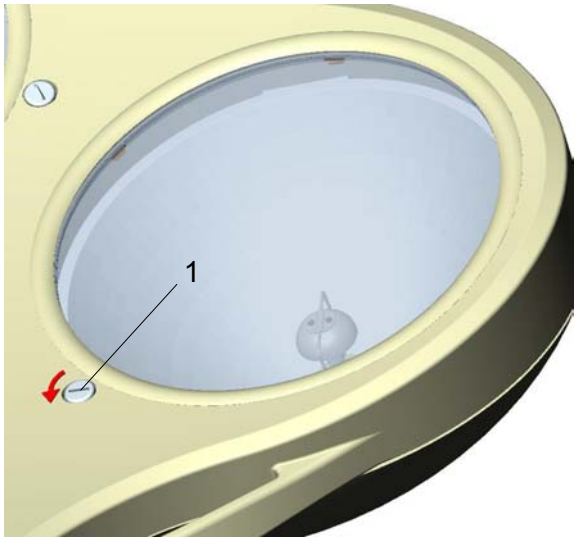
4.2.3 Changing the dispersing lens

The dispersing lens is made of a high-quality plastic. In case the dispersing lens looses its optical characteristics, this can reduce the luminous intensity and the light quality provided.
It may be necessary to exchange the dispersing lens.

Always place the dispersing lens on a soft, non-scratching base to preserve its surface.

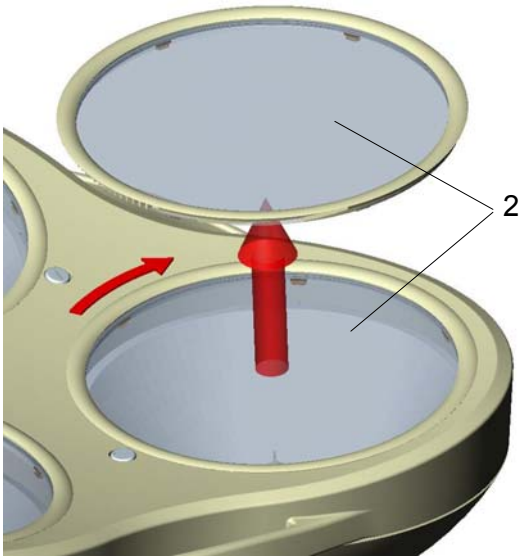
To change the dispersing lens proceed as follows:

- **Turn off the lamp.**
  ATTENTION: Parts of the housing and the halogen bulb may be very hot immediately after use.

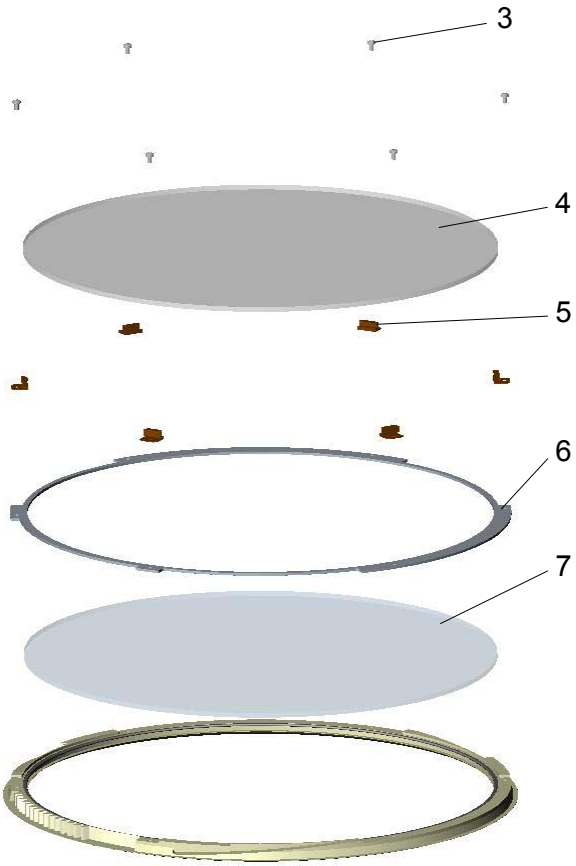


- Turn the lamp, so the light outlets point to the ceiling.
- Turn **screw 1** anticlockwise with an appropriate screw driver.

Remark:
In case there is no screw driver available, you can use a coin.



- By turning the **screw 1** anticlockwise, the **optic ring 2** turns clockwise off the lower housing part.
- Remove the **optic ring 2** by pulling it upwards.

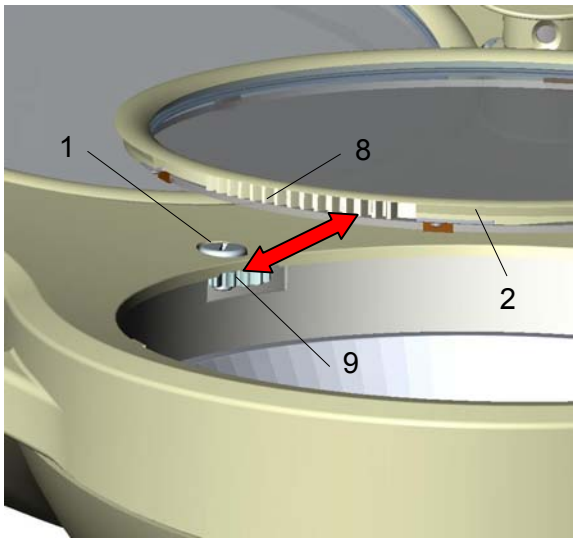


- Loosen the six **screws 3** and remove them.
- Lift the **filter disk 4** off the six **retaining angles 5**.
  Always place the filter disk on a soft, non-scratching base to preserve its surface.

- Remove the six **retaining angles 5**.
- Remove the **retaining ring 6** of the dispersion lens.
- Remove the **dispersion lens 7**.
  Always place the dispersion lens on a soft, non-scratching base to preserve its surface.

- Mount the new **dispersion lens 7**.
  ATTENTION: Only use dispersion lenses, that have been cleaned properly (see chapter 3.2).

- Mount the **retaining ring 6**, the **retaining angles 5**, the **filter disk 4** in reverse order and fix the retaining angles with the six **screws 3**.



- Mount the **optic ring 2** in reverse order (anti-clockwise rotation).
  For mounting position the **optic ring 2**, so the **toothed wheel segment 8** of the ring and the **toothed wheel 9** in the lower housing part work into each other.
- Fix the optic ring by turning the **screw 1** clockwise.

On request of the customer there are spare parts lists and wiring diagrams available for the lamps Mach M5 F / Mach M5 DF.

5. Data

5.1 Technical data

Mach M5 DF / M5 DF/H	
Central light intensity at a distance of 1 meter	160.000 Lux
Light field diameter d_{10}	172,5 mm
Light field diameter d_{50}	96 mm
Light intensity with one shadower	127.500 Lux
Light intensity with two shadowers	85.600 Lux
Light intensity on the ground of a normed tube	157.000 Lux
Light intensity on the ground of a normed tube with one shadower	125.000 Lux
Light intensity on the ground of a normed tube with two shadowers	84.600 Lux
Illumination depth	715 mm
Colour rendering index R_a at 4300 Kelvin	96
Colour rendering index R_9 at 4300 Kelvin	$\geq$ 90
Focusable light field size	17-35 cm
Colour temperature (Kelvin)	4300 K
Radiation intensity in field at 100.000 Lux	380 W/m^2
Temperature increase in head area	2 °C
Total power consumption	231 VA
Number of bulbs: Halogen 22,8/24V 77W	3
Working distance	60-150 cm
Height adjustment	118 cm

5.2 Electrical data

Mach M5 DF / M5 DF/H	
Power consumption	231 W
Voltage AC/DC	22,8 V
Current	10,1 A
Halogen bulb	22,8 V / 77 W
Frequency	50/60 Hz
Degree of protection	Type B
Class of protection	I.

5.3 Environemental conditions

Operation

	Min.	Max.
Temperature	+10°C	+40°C
Relative athmospheric humidity	30 %	75 %
Air pressure	700 hPa	1060 hPa

Transport / storage

	Min.	Max.
Temperature	-10°C	+50°C
Relative athmospheric humidity	20 %	90 %
Air pressure	700 hPa	1060 hPa

5.4 General remarks

When using more than one OT-lamp at the same time (OT-lamp combinations), please make sure that the total radiation intensity in field is less than 1000 W/m^2, to avoid further temperature increase in the wound field.

When installing an OT-lamp, its fail-safety must be guaranteed according to DIN VDE 0100-710 (former DIN VDE 0107).

	Protective conductor

6. CE-mark

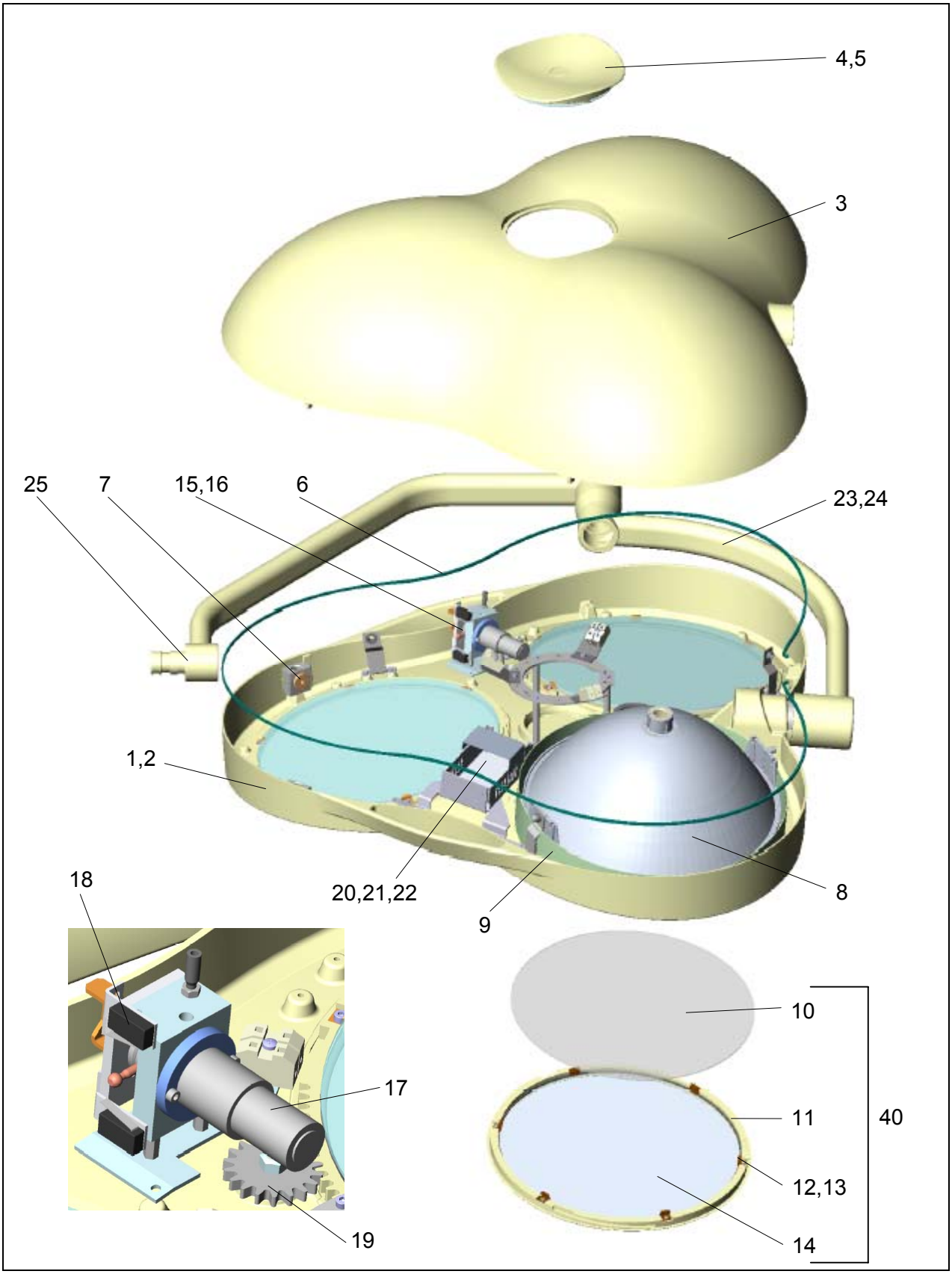
CE

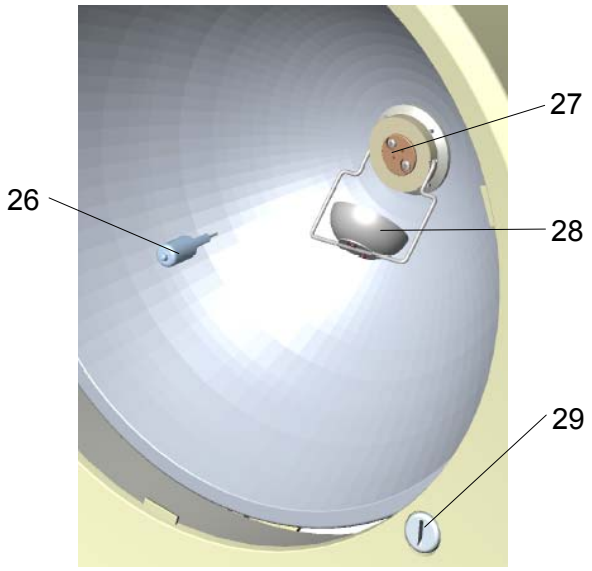
The products Mach M5 comply with the standards 93/42/EEC for medical products of the European Community's Council. Dr. Mach applies the standard EN 60601-2-41.
Dr. Mach GmbH is certified according to DIN EN 46001:1996 and DIN EN ISO 13485:2001.

7. Disposal

The OT-lamp doesn't contain any dangerous goods.
The components of the OT-lamp should be properly disposed at the end of its shelf-life.
Make sure, that the materials are carefully separated.
The electrical conducting boards should be submitted to an appropriate recycling proceeding.
The rest of the components should be disposed according to the contained materials.

8. Spare parts

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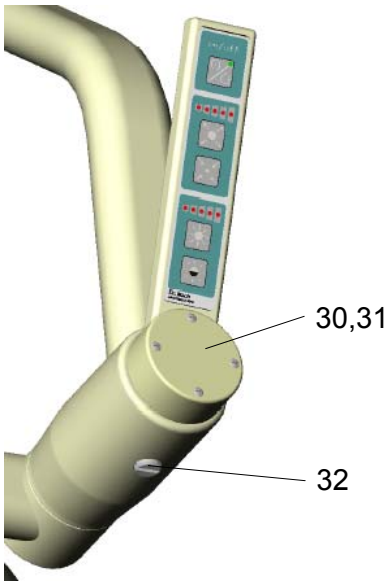
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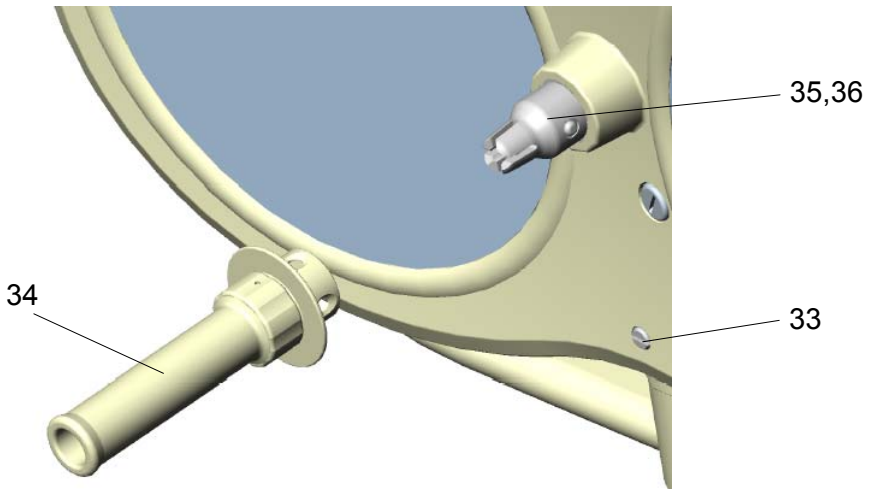
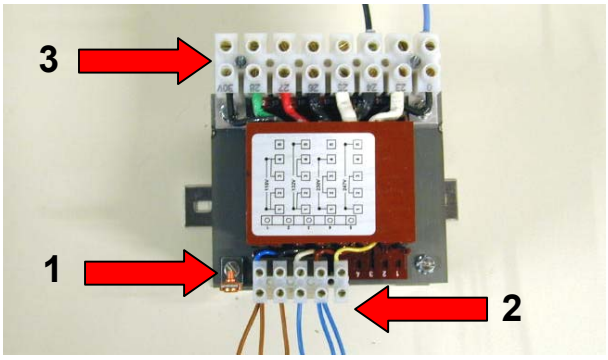

35,36
34
33

9. Spare parts list

Item	Qty.	Name	EDVNO	Remarks
1	1	Lower housing part for lamp without camera	27012201	
2	1	Lower housing part for lamp with camera	27012203	
3	1	Upper housing part	27011201	
4	1	Cover for lamp without camera	27088201	
5	1	Cover for lamp with camera	27088001	
6	1	Sealing cord RAL 5018	27088301	Pasted with upper housing part
7	6	Lock	27087001	
8	3	Reflector	27060204	
9	3	Shielding plate	27022001	
10	3	Conversion filter D284 Califlex Eco	67390204	
11	3	Retaining ring	27021203	
12	18	Retaining angle	27021204	
13	18	Cheese head screw DIN912 M3x6:A2 with laquer	65052098	
14	3	Protective disk	27021201	
15	1	Bowden-control DF	27080002	DF-lamps only
16	1	Bowden-control F	27080001	F-lamps only
17	1	Gear motor	67030108	DF-lamps only
18	2	Micro switch	67340015	DF-lamps only
19	3	Gearwheel	27021202	
20	1	Dimmer board OPLSD I.	67250109	F- ,DF/H lamps with motor control
21	1	Dimmer board OPLSD II.	67250110	F-, DF/H lamps with Bowden-control
22	1	Board OPLSD IV.	67250112	F, DF-lamps without light intensity control
23	1	Lamp bow	27101001	
24	1	Lamp bow for central spring arm	27100001	For low room height
25	1	Cardan bow	27111001	
26	3	Halogen bulb 22,8V / 75W	67100207	
27	3	Ceramic lamp socket with cable	67320007	
28	3	Shadower	27061001	
29	3	Screw	27089203	
30	1	Keypad holder incl. keypad		F/H-lamps only
31	1	Keypad holder incl. keypad		DF/H-lamps only
32	1	Brake screw	21118204	
	1	Press pin	21118003	
33	1	Brake screw	27089205	
	1	Press pin	21118003	
34	1	Sterilisable handle	21150002	
35	1	Coupling for sterilisable handle DF	20220001	DF-lamps only
36	1	Coupling for sterilisable handle F	20220002	F-lamps only
37	1	Toroid transformer 300VA 230V	67010109	To be mounted on the ceiling flange (accessories)
38	1	Block transformer 300VA 230V	67010208	To be mounted inside the transformer housing (accessories)
39	1	Transformer housing for block transformer 300VA	67610101	Not shown (accessories)
40	3	Retaining ring, complete	27021001	Complete with con-version filter and pro-tective disk

10. Appendix
Setting the primary voltage at the block transformer 300VA

Clamps on the transformer



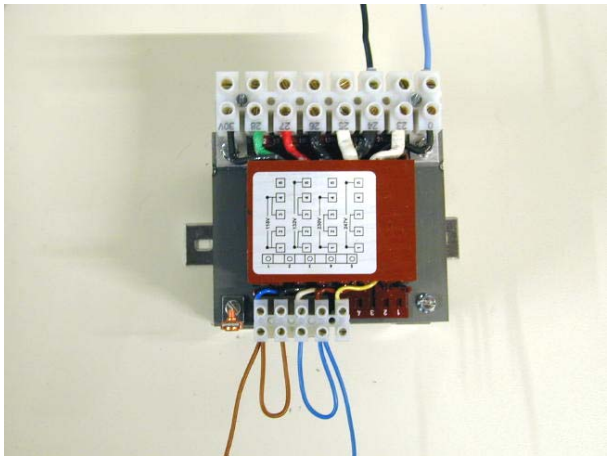
Pos.1 earthing connection at the transformer

Pos.2 primary side

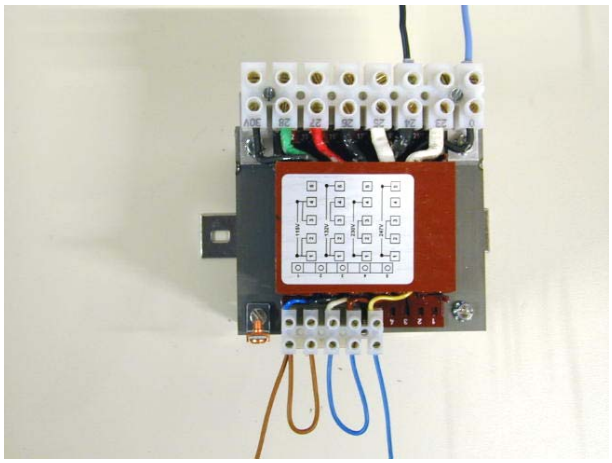
Pos.3 secondary side

- Connect the transformer to earth. Use the provided clamps **pos.1** at the transformer, respectively at the transformer plate.
  See also the explanations on page 19/46 of the mounting instructions "Ceiling and wall attachment" no. 59500001 / edition 05.

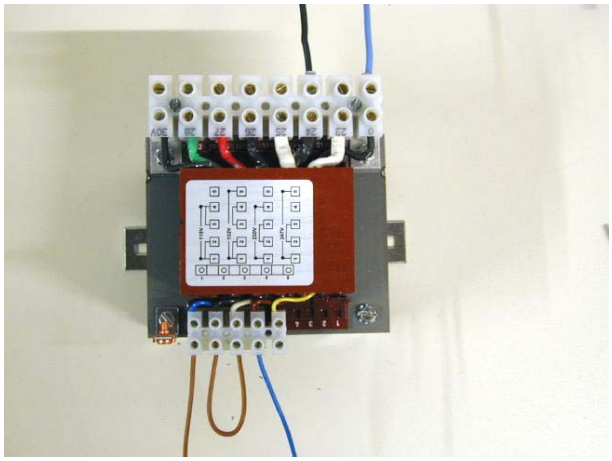
Overview of the possible settings of the primary voltage



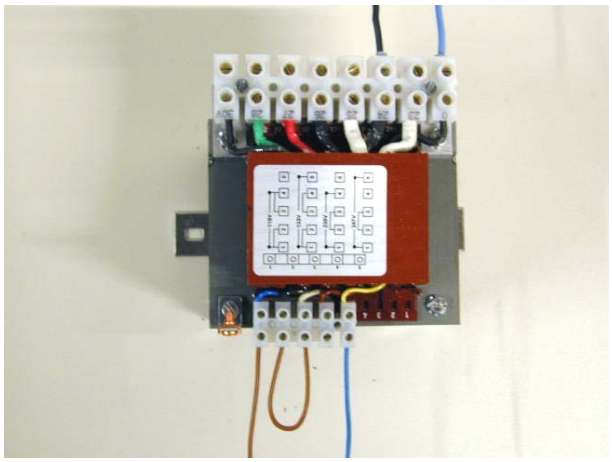
Setting for115V



Setting for 132V



Setting for 230V



Setting for 247V